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DEPARTMENT OF HEALTH AND HUMAN SERVICES

CFN:1124070
Facility ID:11731
Inspection ID #1173170008

Food and Drug Administration
Baltimore District Office
6000 Metro Drive
Suite 101
Baltimore, MD 21215-3215
Telephone: (410) 773-5454

April 19, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Crain Saunders, Assistant Administrator
Huntington Internal Medicine Group
1114 20th Street
Huntington, West Virginia 25703

Dear Mr. Saunders:

A representative from the State of West Virginia, under contract to the Food and Drug Administration (FDA), inspected your facility on March 15, 2002. This inspection revealed a serious regulatory problem involving mammography performed at your facility.

Under a United States Federal law, the Mammography Quality Standards Act (MQSA) of 1992, **[42 U.S.C. 263],** your facility must meet specific requirements for mammography. These requirements help protect the public health by assuring that a facility can perform quality mammography. The following problems were listed on the MQSA Facility Inspection Report issued to your facility at the close of the inspection.

- **Your facility failed to compare the test results of the density difference between the background of the phantom and an added test object to established operating level. [21 CFR 900.12(e)(2)(iv) and 21 CFR 900.12(e)(8)]**

- **Your facility failed to perform a medical audit and outcome analysis for the facility as a whole for all radiologists that read mammograms for Huntington Internal Medicine. [21 CFR 900.12(f)]**

- **Your facility failed to perform a medical audit and outcome analysis separately for each individual radiologist that reads mammograms for Huntington Internal Medicine. [21 CFR 900.12(f)]**

These problems identify a failure to comply with a significant MQSA requirement listed in 21 CFR 900.12(e)(2)(iv), 900.12(e)(8) and 900.12(f). These conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography performed at your facility.

Any response should be submitted to: Food and Drug Administration, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215, to the attention of Steven B. Barber, Compliance Officer.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you may have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715), or through the Internet at http://www.fda.gov.

If you have technical questions about mammography facility requirements, or about the content of this letter, please feel free to contact Elizabeth A. Laudig at (410) 779-5441.

Sincerely,

Lee Bowers
Director, Baltimore District